

Daivobet[®] 50/500 ointment

Dye-vo-bet

Calcipotriol (*Kal-sippo-try-all*)/ Betamethasone (*Beet-ah-meth-ah sown*)

CONSUMER MEDICINE INFORMATION (CMI)

Please read this leaflet carefully before you start your treatment.

Daivobet[®] 50/500 ointment is the brand name. Calcipotriol and betamethasone are the generic names of the combination product, which is Daivobet[®] ointment.

Keep this leaflet. You may want to read it again.

What is in this leaflet?

This leaflet answers some common questions about using the medicine Daivobet[®] ointment. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Daivobet[®] ointment against the benefits it is expected to have for you.

If you have any concerns about using Daivobet[®] ointment, talk to your doctor or pharmacist.

What Daivobet[®] ointment is used for

Daivobet[®] ointment is an anti-psoriasis medicine. Daivobet[®] ointment contains two active ingredients:

- calcipotriol [as monohydrate] (related to Vitamin D)
- betamethasone dipropionate (a corticosteroid).

Daivobet[®] ointment is used only on skin affected by plaque-type psoriasis. Psoriasis is a skin disorder in which skin cells are overactive. The calcipotriol in Daivobet[®] ointment treats the overactive skin cells. The betamethasone dipropionate relieves redness, swelling, itching and irritation of the skin.

Daivobet[®] ointment is used in the type of psoriasis, where “plaques” form in the skin. Plaques are raised, rough, reddened areas covered with fine, dry silvery scales. Plaques are usually about one to two centimetres across.

Daivobet[®] ointment is available only with a doctor’s prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

This medicine is not addictive.

Before you use Daivobet[®] ointment

When you must not use Daivobet[®] ointment

Do not use Daivobet[®] ointment if you have an allergy to:

- calcipotriol
- betamethasone dipropionate
- any of the other ingredients listed at the end of this leaflet (see **Product description**)
- any other similar medicine, such as topical corticosteroids.

Some of the symptoms of an allergic reaction include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or “hives” on the skin.

Do not use Daivobet[®] ointment for severe widespread psoriasis, or the types of psoriasis known as generalised pustular, erythrodermic or exfoliative psoriasis. Your doctor will identify these conditions for you.

Do not use Daivobet[®] ointment if you

- have high blood calcium levels (ask your doctor)
- are taking calcium supplements, drugs to treat calcium deficiency, vitamin D

- supplements or vitamin D-like medicines, for example, calcitriol
- have kidney or liver problems
- have any viral, fungal or bacterial skin infections
- tuberculosis (TB) or syphilis
- perioral dermatitis (red rash around the mouth)
- thin skin, easily damaged skin, stretch marks
- ichthyosis (dry skin with fish like scales)
- acne
- rosacea
- ulcers or broken skin.

Inform your doctor if you are suffering from any illness before using Daivobet[®] ointment.

Do not use Daivobet[®] ointment

- **after the expiry date printed on the pack OR**
- **if it is 12 months after the tube was first opened OR**
- **if the packaging is torn, doesn’t look quite right or shows signs of tampering.**

If any of these apply, return Daivobet[®] ointment to your pharmacist for disposal.

Do not breastfeed if you are using Daivobet[®] ointment on your breasts.

If you are not sure whether you should start using Daivobet[®] ointment, talk to your doctor.

Before you start to use it

Tell your doctor if you have a known allergy to Daivobet[®] ointment, calcipotriol, betamethasone dipropionate or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you

- **are pregnant**
- **are breastfeeding**
- **intend to breastfeed.**

Do not use Daivobet® ointment in children.

Safety and effectiveness of Daivobet® ointment in those below 18 years of age has not been established.

If you have not told your doctor about any of the above, tell him/her before you start using this medicine.

Other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking calcium supplements, drugs to treat calcium deficiency, vitamin D supplements or vitamin D-like medicines, for example calcitriol. Do not use Daivobet® ointment if you are taking these.

Your doctor and pharmacist have more information on medicines you should be careful with or avoid whilst using Daivobet® ointment.

How to use Daivobet® ointment

Follow carefully all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much Daivobet® ointment to use

Apply enough ointment to completely cover the psoriasis plaques.

One fingertip unit (FTU) is enough to cover an area of skin twice the size of your palm. For example, if the area to be treated is 2 elbows and 2 knees, you may require up to 4 FTU's of ointment.

One fingertip unit (FTU) is the amount of ointment, squeezed out of a tube, from the tip of an adult's index finger to the first crease in the finger.



The area treated should not be more than 30% of the body surface area (BSA). (Note: this is approximately the area on one whole leg and one whole arm.)

Discuss this with your doctor.

Do not use more than 15 g in one day.
For example, no more than half (½) of a 30 g tube in one day.

Do not use more than 100 g in one week.
For example, no more than 3 tubes of 30 g in one week.

If you also use other calcipotriol containing products (e.g. Daivobet® gel, Daivonex®) on your body psoriasis, then the **total** amount of calcipotriol products must not exceed 15 g per day or 100 g per week and the total area treated should not exceed 30% of the total body surface.

NOTE: If you use more than the recommended amount of Daivobet® ointment, the levels of calcium in your blood may rise. This is known as "**hypercalcaemia**".

Hypercalcaemia:

- is measured by a blood test
- may be harmful
- may mean that Daivobet® ointment or any other product containing calcipotriol (e.g., Daivonex®) should **not** be used until the calcium level has become normal again.

Blood calcium levels will quickly normalise when your doctor discontinues treatment.

How to use Daivobet® ointment

NOTE: unlike certain other skin preparations, which you use very sparingly, use Daivobet® ointment as follows:

Apply Daivobet® ointment only to the psoriasis plaques in a thin layer and gently rub in. If you accidentally put some of the ointment on normal skin, wash it off as soon as possible.

Do not use Daivobet® ointment

- on large areas of damaged skin
- in skin folds (e.g. groin, underarm)
- on the genitalia
- on the scalp
- inside the mouth, nose or in the eyes
- on the face (an itchy red rash may develop)
- under occlusive dressings (such as a bandage).

The treated area does not need to have a special covering. You may wear your usual clothes.

Wash your hands thoroughly after applying Daivobet® ointment on any part of your body, unless your hands are being treated.

Thoroughly wash your hands prior to handling infants or children.

Take care not to get Daivobet® ointment in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.

Avoid getting Daivobet® ointment on your face, scalp, mouth or eyes accidentally (see above).

If any skin irritation develops, **wash off the Daivobet® ointment.**

When to use Daivobet® ointment

Apply Daivobet® ointment once a day (either morning or night), unless otherwise directed by your doctor.

How long to use it

Continue to use Daivobet® ointment for as long as your doctor tells you.

Each treatment course would normally last for up to four weeks.

Your doctor may decide to stop Daivobet® ointment treatment once your psoriasis has improved, and to recommence it as needed.

If you forget to use it

If you forget to use Daivobet® ointment, use it as soon as you remember. Then go on as before. **If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

If you use too much or use it other than directed (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much or swallowed some of this medicine. **Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

While you are using Daivobet® ointment

Things you must do

While you are using Daivobet® ointment, protect the treated skin areas from sunlight and Ultra Violet (UV) rays, for example, by wearing protective clothing. This is particularly important if your job or lifestyle means you spend time out-of-doors.

If you are going to start any new medicine, tell your doctor and pharmacist that you are using Daivobet® ointment.

If you become pregnant while using Daivobet® ointment, tell your doctor immediately.

Keep all appointments with your doctor so that your progress can be checked.

Your doctor may do blood tests whilst you are using Daivobet® ointment (or any other product containing calcipotriol, for example, Daivobet® gel, Daivonex®). These tests check the levels of calcium in your blood and how well your kidneys are working ("renal function").

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use more than the recommended daily or weekly dose (see How to use Daivobet® ointment).

Do not use other topical corticosteroids (e.g. Advantan®, Diprosone®, Elocon®) on areas treated with Daivobet® ointment.

Side effects

As with all medicines, Daivobet® ointment can cause some side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist:

- **if you have any unpleasant effects while you are using Daivobet® ointment**

or

- **if you notice any of the following and they worry you:**

- skin irritation
- skin peeling
- itching
- skin burning sensation

- skin shrinkage or wasting
- a rash on your face or body
- skin reddening or swelling
- worsening of psoriasis
- infected hair roots
- bruising of skin
- skin pain
- a change in the colour of your skin
- your skin is more sensitive to light
- change in control of diabetes mellitus.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

After using Daivobet® ointment

Keep Daivobet® ointment in the box until required.

Storage

Keep your Daivobet® ointment in a cool dry place where the temperature stays below 25°C. However, do not keep Daivobet® ointment in the refrigerator, as the ointment will not spread easily.

Do not store Daivobet® ointment or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Daivobet® ointment where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any Daivobet® ointment that is left over if:

- your doctor tells you to stop using Daivobet® ointment or
- the tube has been opened for more than 12 months or
- the expiry date has passed.

Product description

What it looks like

Daivobet® ointment is an off-white to yellowish ointment.

Ingredients

Daivobet® ointment contains the active ingredients

- calcipotriol [as monohydrate] (50 microgram/g)
- betamethasone dipropionate (500 microgram/g).

It also contains

- liquid paraffin
- polyoxypropylene-11 stearyl ether
- dl-alpha-tocopherol
- white soft paraffin
- butylated hydroxytoluene (E321).

This is not all the information available on Daivobet® ointment. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Supplier

Daivobet® ointment is supplied in Australia by:

LEO Pharma Pty Ltd,
Brisbane, QLD, Australia
Australian Toll Free No: 1800 991 778

Daivobet® ointment is supplied in New Zealand by:

LEO Pharma Ltd
Auckland New Zealand
New Zealand Toll Free No: 0800 497 456

Daivobet® ointment is manufactured in Ireland.

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